

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration 7200 Lake Ellenor Drive Orlando, FL 32809

Ref: FDA Sample No. 3107890 Customs Entry No. G43-0026596-9 Fresh Artichokes

WARNING LETTER

FLA-97-07

November 22, 1996

Mr. Harold R. Sbrocco Owner, Sbrocco International, Inc. 5 E. Satow Road, Suite C&D Marlton, New Jersey 08053

Dear Mr. Sbrocco:

The Food and Drug Administration (FDA) attempted to examine a shipment of fresh artichokes offered for entry into the United States by your firm on November 5, 1996, under the above referenced entry number, and found that the shipment was not available. Regulation Title 21, Code of Federal Regulations (CFR), Part 1.90, requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. All future entries of FDA regulated products must be filed as formal entries.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. FDA may also request Customs to revoke immediate delivery privileges. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation. In addition, you should inform Customs and FDA if and when redelivery is accomplished.

Mr. Harold R. Sbrocco Page 2 November 22, 1996

Your written reply should be addressed to the Food and Drug Administration, Attention: Paul R. Bagdikian, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Douglas D. Tolen Director, Florida District